

Application No.: 10/081,555

Attorney Docket No.: SALK2270-5
(088802-5212)

Filing Date: February 20, 2002

Amendment in Response to Office Action (mailed 5/3/05) faxed 6/3/05

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Remarks

The present invention is based on the discovery and characterization of a new class of receptors that are part of the steroid/thyroid hormone superfamily of receptors, a representative member of which has been designated SXR (or "steroid X receptor"). Invention receptors are characterized by:

forming a heterodimer with retinoid X receptor (RXR),

binding to a (direct or inverted) repeat response element motif based on the half site AGTTCA,

activating transcription through response elements found in steroid inducible P450 genes in response to a wide variety of natural and synthetic steroid hormones, and

being prominently expressed in the liver and the intestine.

Specifically, the present invention is directed to screening assays for determining whether a test compound (or a combination of test compounds), will modulate the activity of the invention SXR polypeptide. The assay comprises contacting a host cell line containing an SXR receptor polypeptide, preferably a human or rabbit cell line, with one or more test compound(s) in an appropriate culture medium, wherein the host cell line further contains a reporter vector comprising a promoter that is operable in the cell line operatively linked to an invention SXR response element for activation thereof, and DNA encoding a reporter protein operatively linked to the promoter for transcription of the DNA. The invention assay further includes determining whether the reporter protein is present (i.e., expressed by the cell line), wherein a determination that the reporter is present indicates the test compound activates the SXR polypeptide (i.e., an agonist), and a determination that the reporter is not present in the assay predicts the test compound does not activate the invention SXR polypeptide (i.e., not an agonist).

By the present communication, claims 32 and 35-37 have been amended, and claims 38-40 have been added to define Applicants' invention with greater particularity. No new matter is added by the subject amendments as all amended and new claim language is fully supported by the specification and original claims.

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In view of the above amendments, claims 2-5, 27-29 and 32-40 are now pending, with claims 4 and 32-34, 36 and 37 under active consideration and claims 2, 3, 5, 27-29, 35 and 38-40 presently being withdrawn, subject to Applicants' request for rejoinder thereof. A complete set of claims is provided herewith in the Listing of Claims, beginning on page 2 of this communication.

The further requirement under 35 U.S.C. § 121 for election of a single disclosed species from each of Groups a (promoters), b (response elements) and c (reporter protein), is respectfully traversed.

It is respectfully submitted that the specific promoters, response elements and reporter proteins employed in the invention assays are relatively unimportant. One of skill in the art could readily identify numerous promoters, response elements and reporter proteins which are suitable for use in the practice of the present invention. What is important to conduct the invention assays is the presence of the invention receptor, the SXR polypeptide, as is clearly required by all of the currently pending claims. Dependent claims 32-40 have been presented herein merely to define Applicants' invention with greater particularity.

Accordingly, reconsideration and withdrawal of the requirement for election of species are respectfully requested.

However, in order to be fully responsive, and to facilitate initiation of substantive prosecution of this application, Applicants hereby elect a CYP3A cellular promoter (as the species of promoter; see claim 32 as amended herein), SEQ ID NO:3 (as the response element; see claim 36 as amended herein), and luciferase (as the reporter protein; see claim 37 as amended herein).

In view of the amendments submitted herewith, it is requested that at least claims 2 and 27-29 and 33-40 also be prosecuted in conjunction with elected claim 4.

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Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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